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## II. REMARKS

This application is a continuation of patent application Serial No. 191,807. The claims therein -- including an ultrasonic probe and associated sleeve -- were deemed patentable over the prior art, and the application was issued as U.S. Patent No. 6, 224,565 on May 2, 2001, for "Protective Sheath and Method for Ultrasonic Probes."

Claims 12 – 17 are currently pending in this application. Claim 12, the sole independent claim in this case, states:

12. A protective sheath for use with an elongate ultrasonic probe of an ultrasonic fragmenting device, said device having a housing and an ultrasonic horn within and attached to said housing, wherein the elongate ultrasonic probe is configured for attachment to the ultrasonic horn, has an outer surface about and along its length, has vibratory nodes spaced along its length, and has a flange that circumscribes the elongate ultrasonic probe at or near the most distal vibratory node of the probe, said protective sheath comprising:

a continuous hollow sleeve having a proximal end and a distal end, said sleeve being configured to surround the elongate ultrasonic probe and extend therealong when said sleeve and probe are aligned;

a connection on the proximal end of the hollow sleeve to connect the hollow sleeve to the housing;

an inner surface of the hollow sleeve formed, shaped, and sized to prevent contact with the outer surface of the elongate ultrasonic probe along its length so that there is generally a clearance between the inner surface and the outer surface when said sleeve and probe are aligned; and

said inner surface having an inside diameter adjacent the flange, when the sheath is aligned with the probe, that is generally and substantially the same as the outside of the flange thereby forming generally a barrier to the passage of material into the clearance.

(emphasis added.) The claims have been rejected in the Office Action and the rejection has been made final. Because it appears that the extant issues are primarily legal and the Office Action

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has fully explicated the Patent Office's legal position for the first time, applicant has filed this request for continued prosecution and has concurrently filed this Response explaining why the Patent Office's legal position is in error.

Claims 12 and 14-17 stand rejected under 35 U.S.C. § 102 as being anticipated by the Mackool Patent (i.e., U.S. Patent No. 5,354,265). (Office Action, p. 2.) Claim 13 was rejected under 35 U.S.C. § 103 as being unpatentable over the Mackool Patent in view of Hood et al. (i.e., U.S. Patent No. 5,746,713). (Office Action, p. 3.)

As noted by applicant in its prior response, these rejections are not factually supported by the references. The Mackool Patent does not anticipate the subject matter of Claims 12 and 14-17 and is not a proper primary reference for the obviousness of Claim 13. Mackool does not show a sleeve having all of the features of Claim 12. For example, the claim requires a sleeve that cooperates with the flange "thereby forming generally a barrier to the passage of material into the clearance" between the sleeve and the probe. In contrast Mackool shows a "ported" device that deliberately permits the flow of material between the space between the sleeve and the instrument and the tissue being operated on. (See, e.g., Abstract and Fig. 1, item 20.)

The Office Action does not respond substantively to these distinctions. It merely states that "Mackool teaches a continuous sleeve 18 as claimed, wherein the sleeve can be made out of rigid plastic or 'other suitable material' . . . ." (Office Action, p.2.) Again, it is apparent that the Patent Office believes that Mackool is sufficient to anticipate Claim 12, because the preamble of that claim is merely a statement of functional use and is not otherwise a part of the claim. (Office Action, pp. 3-5.) With all due respect this is not correct.

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With respect to whether the preamble is part of the claim, the Federal Circuit has said, in general, that:

Language in a claim preamble ... acts as a claim limitation only when such language serves to "give meaning to a claim and properly define the invention," not when the preamble merely states a purpose or intended use of the invention.

(Apple Computer, Inc. v. Articulate Systems, Inc., 234 F.3d 14, 57 USPQ2d 1057 (Fed. Cir. 2000) citing In re Paulsen, 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994). See also, Catalina Marketing International, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 62 USPQ2d 1781 (Fed. Cir. 2002) summarizing the case law on this point.)

More specifically and to the point, the Federal Circuit has explained that:

Where a patentee uses the claim preamble to recite structural limitations of his claimed invention, the PTO and courts give effect to that usage.

(Rowe v. Dror, 112 F.3d 473, 42 USPQ2d 1550 (Fed. Cir. 1997); emphasis added.)

When the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects.

(Rockwell International Corp. v. United States, 147 F.3d 1358, 47 USPQ2d 1027 (Fed. Cir. 1998).)

As stated by Professor Chisum in his treatise:

In general, it seems that a preamble will be considered a limitation if the claim cannot be read independently of the preamble and the preamble must be read to give meaning to the claim or is essential to point out the invention.

(Chisum on Patents, § 8.06[I][d]; emphasis added.) In this case the preamble is clearly part of the claim for a number of reasons.

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First, the preamble does not just set forth a function for the invention in the body of the claim. For example, the preamble does not merely state that the sheath is "for use with an elongate ultrasonic probe." It goes far beyond that.

Second, the preamble recites specific structural features of that probe including, among other things: "an outer surface about and along its length" and "a flange that circumscribes the elongate ultrasonic probe at or near the most distal vibratory node of the probe."

Third, elements recited in the preamble are referred to in the body of the claim. Thus the Claim 12 requires "an inner surface of the hollow sleeve formed, shaped, and sized to prevent contact with the outer surface of the elongate ultrasonic probe along its length so that there is generally a clearance between the inner surface and the outer surface when said sleeve and probe are aligned." The claim also specifies the "inner surface having an inside diameter adjacent the flange, when the sheath is aligned with the probe, that is generally and substantially the same as the outside of the flange thereby forming generally a barrier to the passage of material into the clearance. Thus, the body of the claim refers to the probe and the elements of the probe, e.g., the "outer surface" and "flange" originally recited in the preamble.

Fourth, the body of Claim 12 could not be read without reference to the preamble.

Clearly, the preamble of Claim 12 does not merely state a function for a structure that is completely and independently defined by the elements set forth in the body of the claim. This is clearly distinguishable from the fact situations in the two cases cited in the Office Action for the first time. In re Casey (CCPA 1967) involved a claim in which the body set forth a structure completely and independently of the preamble and the applicant attempted to distinguish that old

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structure by the function set forth in the preamble of the claim. Essentially, Casey attempted to claim a new use for an old device by slapping a new purpose in the preamble of a claim to an old structure. Similarly, In re Otto (CCPA 1963) involved a claim in which the method steps in the body of the claim could be read independently of the preamble. Unlike the claims in the cases cited by the Patent Office, the claims at issue here cannot be read independently of the preamble which includes structural elements that are referred to again in the body of the claim.<sup>1</sup>

With all due respect, applicant submits that pending, independent Claim 12 is like the acceptable, hypothetical "Claim 1" set forth on page 4 of the Office Action. Instead of reciting a sheath with an "inwardly protruding members that line up with the nodes of the probe when assembled," Claim 12 states: (a) "an inner surface of the hollow sleeve formed, shaped, and sized to prevent contact with the outer surface of the elongate ultrasonic probe along its length so that there is generally a clearance between the inner surface and the outer surface when said sleeve and probe are aligned" and (b) an "inner surface having an inside diameter adjacent the flange, when the sheath is aligned with the probe, that is generally and substantially the same as the outside of the flange thereby forming generally a barrier to the passage of material into the clearance. Thus, features in the body of the claim can only be read by using the elements and limitations of the preamble. Claim 12 is exactly like the acceptable, hypothetical claim proposed in the Office Action.

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<sup>1</sup> Indeed, courts have held that the preamble may be part of a claim, even where the preamble does not set forth elements later referred to in the body of the claim. (See, e.g., General Electric Co. v. Nintendo Co., Ltd., 179 F.3d 1350, 50 USPQ2d 1910 (Fed. Cir. 1999).)

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For all of these reasons, applicant respectfully submits that the Office Action is clearly incorrect as a matter of law in not considering the preamble as part of the claims at issue here. Simply stated, it is impossible to read the claims at issue without reference to elements set forth in the preamble. For this reason the rejections under 35 U.S.C. §§ 102 and 103 should be withdrawn. The prior art does not show all of the elements of the claimed invention and does not render obvious the subject matter as a whole.<sup>2</sup>

### III. CONCLUSION

For the reasons set forth above, applicant respectfully submits that the claims are in condition for allowance; that the rejection be withdrawn and that a notice of allowance be issued.

It is applicant's belief that no fee (other than that associated with the accompanying request for extension of time and the request for continued examination) is required in association with this Response. However any deficiency should be credited, or overpayment debited, to Account No. 04-1415 — with reference to Docket No. 40206.0001USC1.

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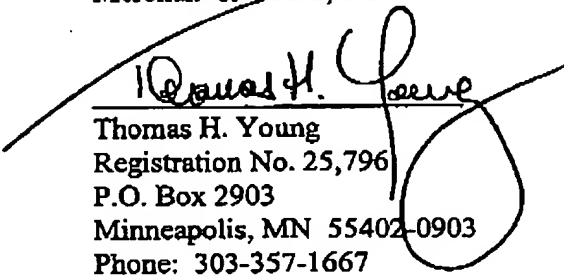
<sup>2</sup> If the Patent Office action has another objection to the claimed subject matter, it should set that forth rather than attempting to ignore the relationship of elements of the sheath set forth in the body of the claim to elements of the probe established in the preamble.

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Respectfully submitted this 29<sup>th</sup> day of May 2003.



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